

杭州东瑞医药科技有限公司
HANGZHOU DAWN RAY PHARMACEUTICAL CO.,LTD.

CERTIFICATE OF ANALYSIS

Azithromycin dihydrate

Batch No.: DR20130313	Quantity : 0.5kg
Manufacture Date: 2013.03.13	Expiry Date: 2017.03.13

TESTS:

Items	Specification	Results
Appearance	White or almost white powder	white powder
Solubility	Practically insoluble in water, freely soluble in anhydrous ethanol and in methylene chloride	Conforms
Identification		
IR	Conforms to azithromycin RS	Conforms
HPLC	Conforms to azithromycin RS	Conforms
Crystallinity	Meets the requirements	Conforms
PH	9.0-11.0	10.03
Specific optical rotation	-45° ~ -49°	-46.8°
Heavy metals	≤25ppm	<25ppm
Water	4.0-5.0%	4.4%
Residue on ignition	≤0.3%	0.07%
Limit of related substances		
Azithromycin-N-oxide	≤0.5%	N.O.
3'-(N-N-Didemethyl-3'-N-formylazithromycin	≤0.5%	0.04%
3'-(N-N-Didemethyl) azithromycin(aminoazithromycin)	≤0.5%	0.02%
Azithromycin related compound F	≤0.5%	0.04%
Desosaminylazithromycin	≤0.3%	0.04%
N-demethylazithromycin	≤0.7%	N.O.
Azithromycin C	≤0.5%	0.10%
3'-De(dimethylamino)-3'-oxoazithromycin	≤0.5%	N.O.
Azaerythromycin A	≤0.5%	N.O.
Azithromycin impurity P	≤0.2%	0.01%
2-desethyl-2-propylazithromycin	≤0.5%	0.07%
3'-n-demethyl-3'-n-[(4-methylphenyl) sulfonyl]Azithromycin	≤0.5%	0.19%
Azithromycin B	≤1.0%	N.O.

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Any individual ,unidentified impurity	≤0.2%	Conforms
Total Impurity	≤3.0%	1.03%
Residue solvents		
Methanol	≤0.3%	0.0374%
Ethanol	≤0.05%	N.O.
Acetone	≤0.5%	0.0584%
Chloroform	≤0.006%	N.O.
Assay	945-1030μg/mg Azithromycin(C38H72N2O12) on the anhydrous basis	contains on the 983μg/mg
Conclusion: The results conform with the USP35.		

Analyst: Joe Yu Checker: Agnes Zhong QA.Manager: Sun Wenhui



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